



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/518,753

06/30/2005

Joanne J. Fillatti

16518.162

8074

28381 7590 08/28/2008

ARNOLD & PORTER LLP
ATTN: IP DOCKETING DEPT.
555 TWELFTH STREET, N.W.
WASHINGTON, DC 20004-1206

EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

08/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,753	Applicant(s) FILLATTI, JOANNE J.	
	Examiner Elizabeth F. McElwain	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-18 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-14 and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claims 15-18 drawn to an invention nonelected with traverse in the reply filed on November 30, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 3, 6, 8, 9, 13, 20 and 21 are currently amended.

Claims 22 and 23 are newly submitted.

Claims 1, 2 and 19 are cancelled.

Claims 3-18 and 20-23 are pending.

Claims 3-14 and 20-23 are drawn to the elected invention and are examined on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3-14, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 3 and 13, for the recitation of “complements thereof, and fragments of either” with regard SEQ ID NO: 1, is withdrawn in view of the amendment

Art Unit: 1638

of the claims, and in view of the definition of “complement” in the specification as referring the complement of the sequence along its’ complete length.

The rejections of claims 10, 11 and 14 as indefinite are withdrawn in view of applicants’ arguments pointing to definitions in the specification for the terms in the claims.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3-14 and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

5. The claims are drawn to a soybean plant transformed with any polynucleotide that has 95% or greater identity to at least 100 contiguous nucleotides of SEQ ID NO: 1 or complements thereof, wherein the plant produces seed with more oleic acid than a plant with a similar background but lacking said nucleic acid. The specification only describes a soybean plant that is transformed with SEQ ID NO: 1, which is identified as the FAD2-1A intron, operably linked to a heterologous promoter in sense or anti-sense orientation, wherein the plant produces seed with more oleic acid than a plant with a similar background but lacking said nucleic acid, including oleic acid levels of about 30% to 60% with one example of an oleic acid level of 80%.

Art Unit: 1638

The specification does not describe any other sequences that have at least 95% or greater identity to at least 100 contiguous nucleotides of SEQ ID NO: 1 in a soybean plant having more oleic acid in the plant seed than in seeds of a similar plant that is not transformed with the same sequence. Applicants' are claiming an entire genus of soybean plants comprising a multitude of possible sequence constructs that result in plants having the specified characteristic of increased oleic acid. However, the specification only describes one specific sequence transformed into a soybean plant, wherein the soybean plant has increased oleic acid in the seed.

“A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” In addition, “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention”. See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

6. Claims 3-14, and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a soybean plant transformed with any polynucleotide that has 95% or greater identity to at least 100 contiguous nucleotides of SEQ ID NO: 1 or complements thereof, wherein said

Art Unit: 1638

soybean plant produces seeds having increased oleic acid for the reasons set forth in the last office action.

7. Applicants' arguments filed May 27, 2008 have been fully considered but they are not persuasive. Applicants' argue that soybean plants transformed with SEQ ID NO: 1 in sense and antisense and having increased levels of oleic acid are disclosed in Table I, wherein the sense constructs of SEQ ID NO: 1 are called pCGN5469, and the anti-sense SEQ ID NO: 1 constructs are called pCGN5471. The Examiner maintains that the specification is unclear in reciting the numbers "5469" and "5471" in Table I without any statement that these numbers referred to soybean plants transformed with pCGN5469 or pCGN5471. The specification is also unclear at the first line of page 44, where it refers to a "FAD2-1A intron" without a sequence identifier, wherein this "FAD2-1A intron" is cloned into pCGN3892, then into pCGN9372 and then into pCGN5469 and pCGN5471. The specification does not make clear that the sequences cloned into pCGN5469 and pCGN5471 are the same as the FAD2-1A sequence identified as SEQ ID NO: 1 that is amplified (line 25 of page 43), and the complement thereof. If the FAD2-1A sequence that is cloned into pCGN3892 is SEQ ID NO: 1, then the specification should be amended to recite "SEQ ID NO: 1" after the recitation of FAD2-1A in the first line of page 44.

8. Applicants further argue that the specification provides for numerous constructs to produce the desired fatty acid profile, and that the claims are drawn to the plants, not to a method. Applicants also argue that one of skill in the art could make nucleotide substitutions to SEQ ID NO: 1 without undue experimentation. The Examiner maintains that there is a high level of unpredictability in modifying fatty acid composition by transforming a plant with a nucleic acid, and that the claims encompass a very large number of soybean plants having any of

Art Unit: 1638

a multitude of possible nucleic acid sequences that may be any of 100 consecutive nucleotides of SEQ ID NO: 1 or larger fragments and further having nucleotide substitutions in as many as 5% of the nucleotides. As set forth in the last office action, the prior art teaches the high level of unpredictability of modifying plant phenotypes with sequences that are not identical to the endogenous sequences, and the specification fails to provide examples or guidance with regard to choosing from the large number of soybean plants transformed with any of a vast number of nucleotide sequences. Therefore, it would require undue experimentation to make and/or use the claimed invention.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1638

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EFM

/Elizabeth F. McElwain/

Primary Examiner, Art Unit 1638